

Dr. Marwa
27/5/2021
Alaa Mahdy

1. Name of the medicinal product

Tadalafil

2. Qualitative and quantitative composition

Each 10 mg tablet contains 10 mg tadalafil.

Each 20 mg tablet contains 20 mg tadalafil.

3. Pharmaceutical form

Film-coated tablet.

Tadalafil 10 mg Film-coated tablet:

light yellow to yellow, almond – shaped, biconvex, unscored, film coated tablet with white to off white core.

Tadalafil 20 mg Film-coated tablet:

light yellow to yellow, almond – shaped, biconvex, unscored, film coated tablet with white to off white core.

4. Clinical particulars

4.1 Therapeutic indications

Treatment of erectile dysfunction in adult males.

In order for tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required.

5 mg only: Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males.

Tadalafil is not indicated for use by women.

4.2 Posology and method of administration

Posology

Erectile dysfunction in adult Men

In general, the recommended dose is 10 mg taken prior to anticipated sexual activity and with or without food.

In those patients in whom tadalafil 10 mg does not produce an adequate effect, 20 mg might be tried. It may be taken at least 30 minutes prior to sexual activity.

The maximum dose frequency is once per day.

Tadalafil 10 and 20 mg is intended for use prior to anticipated sexual activity and it is not recommended for continuous daily use.

Special populations

Elderly Men

Dose adjustments are not required in elderly patients.

Men with Renal Impairment

Dose adjustments are not required in patients with mild to moderate renal impairment. For patients with severe renal impairment, 10 mg is the maximum recommended dose.

Men with Hepatic Impairment

the recommended dose of TADALIPTIS is 10 mg taken prior to anticipated sexual activity and with or without food. There is limited clinical data on the safety of TADALIPTIS in patients with severe hepatic impairment (Child-Pugh class C); if prescribed, a careful individual benefit/risk evaluation should be undertaken by the prescribing physician. There are no available data about the administration of doses higher than 10mg of tadalafil to patients with hepatic impairment.

Men with Diabetes

Dose adjustments are not required in diabetic patients.

Paediatric population

There is no relevant use of TADALIPTIS in the paediatric population with regard to the treatment of erectile dysfunction.

Method of administration

TADALIPTIS 10, and 20 mg film-coated tablets for oral use.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

- Hypersensitivity Reactions Due to Usage Such As

1- Stevens-Johnson Syndrome

2- Exfoliative Dermatitis

In clinical studies, tadalafil was shown to augment the hypotensive effects of nitrates. This is thought to result from the combined effects of nitrates and tadalafil on the nitric oxide/cGMP pathway.

Therefore, administration of TADALIPTIS to patients who are using any form of organic nitrate is contraindicated (see section 4.5).

TADALIPTIS must not be used in men with cardiac disease for whom sexual activity is inadvisable.